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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,773	06/07/2001	James E. Darnell JR.	600-1-195C	9919
23565	7590	10/16/2006	EXAMINER	
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			NOAKES, SUZANNE MARIE	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/876,773

Applicant(s)

DARNELL ET AL.

Examiner

Suzanne M. Noakes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 69-96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1 and 69-96 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Upon further consideration, the Examiner hereby withdraws and vacates the restriction requirement of the 24 March 2006 in lieu of the following restriction requirement.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claim 1, drawn to a receptor recognition factor, classified in class 530, subclass 350.
 - II. Claims 69, 70 and 78, drawn to a recombinant DNA molecule encoding a receptor recognition factor (RRF) protein with four or more consecutive amino acids selected from (a)-(pp) from SEQ ID No: 2 or 4, classified in class 536, subclass 23.1. Note: Applicant is required to select ONE sequence from (a)-(pp) for claims 69 and 70. This is NOT an election of species.
 - III. Claim 71, drawn to drawn to a recombinant DNA molecule encoding a receptor recognition factor (RRF) protein with five or more consecutive amino acids selected from (a)-(x) from SEQ ID No: 2 or 4, classified in class 536, subclass 23.1. Note: Applicant is required to select ONE sequence from (a)-(x). This is NOT an election of species.
 - IV. Claim 72, drawn to a recombinant DNA molecule encoding a receptor recognition factor (RRF) protein with six or more consecutive amino acids selected from (a)-(o) from SEQ ID No: 2 or 4, classified in class 536,

- subclass 23.1. Note: Applicant is required to select ONE sequence from (a)-(o). This is NOT an election of species.
- V. Claim 73, drawn to a recombinant DNA molecule encoding a receptor recognition factor (RRF) protein with seven or more consecutive amino acids selected from (a)-(j) from SEQ ID No: 2 or 4, classified in class 536, subclass 23.1. Note: Applicant is required to select ONE sequence from (a)-(j). This is NOT an election of species.
- VI. Claim 74, drawn to a recombinant DNA molecule encoding a receptor recognition factor (RRF) protein with eight or more consecutive amino acids selected from (a)-(f) from SEQ ID No: 2 or 4, classified in class 536, subclass 23.1. Note: Applicant is required to select ONE sequence from (a)-(f). This is NOT an election of species.
- VII. Claim 75, drawn to a recombinant DNA molecule encoding a receptor recognition factor (RRF) protein with nine or more consecutive amino acids selected from (a)-(c) of SEQ ID No: 2 or 4, classified in class 536, subclass 23.1. Note: Applicant is required to select ONE sequence from (a)-(c). This is NOT an election of species.
- VIII. Claim 76, drawn to a recombinant DNA molecule encoding a receptor recognition factor (RRF) protein with ten or more consecutive amino acids selected from (a)-(b) of SEQ ID No: 2 or 4, classified in class 536, subclass 23.1. Note: Applicant is required to select ONE sequence from (a)-(b). This is NOT an election of species.

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- IX. Claim 77, drawn to a recombinant DNA molecule encoding a receptor recognition factor (RRF) protein with eleven or more consecutive amino acids selected of SEQ ID No: 2 or 4, classified in class 536, subclass 23.1.
Note: Applicant is required to select ONE sequence from (a)-(pp). This is NOT an election of species.
- X. Claim 79, drawn to a recombinant DNA molecule encoding a receptor recognition factor (RRF) protein which said DNA molecule is capable of hybridizing to SEQ ID No: 1 under standard conditions, classified in class 536, subclass 23.1.
- XI. Claim 80, drawn to a recombinant DNA molecule encoding a receptor recognition factor (RRF) protein which said DNA molecule is capable of hybridizing to SEQ ID No: 3 under standard conditions, classified in class 536, subclass 23.1.
- XII. Claim 81-95, drawn to a recombinant DNA molecule encoding a receptor recognition factor (RRF) wherein the RRF contains one or more of the boxed regions of Figure 8B, classified in class 536, subclass 23.1. Note: Applicant is required to select ONE of the boxed regions. This is NOT an election of species.
- XIII. Claim 96, drawn to a method of purifying the recombinant RRF protein of Group XII, classified in class 530, subclass 412+.

The inventions are distinct, each from the other because of the following reasons:

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3. Inventions II-XII are related as products which share an alleged common utility of a recombinant DNA molecule encoding an RRF but the common utility is NOT linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, each DNA molecule encodes completely separate structures identified by having four or more amino acids that are the same in both SEQ ID No: 2 or 4. Thus, there is no common structural feature among each of the separate fragments claimed and each different DNA will encode a separate protein with its own unique structure. If, however, there is a common unifying structural feature (e.g. amino acid sequence) which the Examiner has inadvertently missed, Applicants are welcome to point out which of the fragments of four or more, five or more, etc. are functionally and structurally the same or equivalents and to state that each fragment is thus an obvious variant over all others. However, in the absence of such a unifying feature, because each DNA molecule encodes a protein having a unique individual structure, the time, money and search burden upon the Examiner and the USPTO sequence database searching personnel, is huge because each sequence (e.g. all 43 overlapping 'four or more' sequences, or all 24 'five or more' overlapping sequences, etc.) has to be searched in separate DNA and protein databases which does not produce a co-extensive search. As a very minimal example, a crude search of 'HQLY' came up with 5052 hits which the Examiner would have to analyze in great depth. Having to search the other 42 'four or more' potential sequences (see Claim 70), five or

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more, etc. would likely have a similar number of hits and thus it would be nearly impossible for the Examiner to efficiently and accurately search the claims without an enormous undue search burden. Finally, it should be noted that the products of each group can be utilized in completely separate assays or to be used in different hybridization experiments which would give unique results and thus each is separately patentable and distinct.

4. Inventions I and II-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the DNA of group II-XII is related to the protein of group I by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

5. Inventions I and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the RRF

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protein can be used in a multitude of other processes such as in protein crystallization trials or *in vitro* binding assays.

6. Inventions II-XII and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation because the DNA merely encodes for the protein to be purified, however, the DNA itself is not used in the method of purifying the protein. As such the two Groups would not be co-extensive in the requisite search which would place an undue search burden upon the examiner.

7. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

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record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.00am to 3.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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04 October 2006

Karen Cochrane Carlson

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER